Paper No. 30

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte SURYA K. GOLI,
JENNIFER L. HILLMAN and
LYNN E. MURRY

Appeal No. 2003-1847
Application No. 09/203,548

ON BRIEF

Before WILLIAM F. SMITH, MILLS and GRIMES, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 18-19 and 33-34, which are all of the claims pending in this application. Claims 20-32 and 35-42 are also pending, but have been withdrawn from consideration by the examiner.

Claim 18 is illustrative of the claims on appeal and reads as follows:

18. A purified polypeptide comprising an amino acid sequence selected from the group consisting of:

a) an amino acid sequence of SEQ ID NO:1;

(b) a naturally-occurring amino acid sequence having at least 95% sequence identity to the sequence of SEQ ID NO:1, wherein said amino acid sequence encodes a polypeptide whose expression is upregulated by 2,3,7,8,-Tetrachlorodibenzo-p-dioxin,

(c) a biologically-active fragment of the amino acid sequence of SEQ ID NO:1, wherein said fragment encodes a polypeptide whose expression is upregulated by 2,3,7,8,-Tetrachlorodibenzo-p-dioxin, and

(d) an immunologically active fragment of the amino acid sequence of SEQ ID NO:1 wherein said fragment generates an antibody that specifically binds to the polypeptide encoded by SEQ ID NO:1.

The references relied upon by the examiner are:

Jacobs et al. (Jacobs) 5,976,837 Nov. 2, 1999

Friedberg, et al. (Friedberg), "Sequence of a novel cytochrome CYP2B cDNA coding for a protein which is expressed in a sebaceous gland, but not liver," Biochem J., Vol. 287, pp. 775-783 (1992)

Meyer et al. (Meyer), "Purification and partial sequencing of high-affinity progesterone binding site(s) from porcine liver membranes," Eur. J. Biochem., Vol. 239, pp. 726-731 (1996)

Falkenstein et al. (Falkenstein), "Full-length cDNA sequence of a progesterone membrane-binding protein from porcine vascular smooth muscle cells," Biochemical and Biophysical Research Communications, Vol. 229, pp. 86-89 (1996)

Selmin et al. (Selmin), "Isolation and characterization of a novel gene induced by 2,3,7,8-tetrachlorodibenzo-p-dioxin in rat liver, Carcinogenesis, Vol. 17, No. 12, pp. 2609-2615 (1996)

The references relied upon by the appellants are:

Wehling, "Specific, Nongenomic Actions of Steroid Hormones," Ann. Rev. Physiology, Vol. 59, pp. 365-393 (1997)

Jacobs et al. (Jacobs) 5,976,837 Nov. 1999

Grounds of Rejection

1. Claims 18-19 and 33-34 stand rejected under 35 U.S.C. §101 for lack of utility.

2. Claims 18-19 and 33-34 stand rejected under 35 U.S.C. §112, first paragraph for lack of enablement.

3. Claims 18 and 33 stand rejected under 35 U.S.C. §112, first paragraph for lack of written description in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

4. Claims 18 and 33 stand rejected under 35 U.S.C. §102(a) as anticipated by Meyer as evidenced by Falkenstein.

5. Claims 18 and 33 stand rejected under 35 U.S.C. §102(e) as anticipated by Jacobs.

We affirm the rejections of claims 18-19 and 33-34 under 35 U.S.C. §101 for lack of utility and 35 U.S.C. §112 for lack of enablement. We do not reach the rejections under 35 U.S.C. §112 for lack of written description and 35 U.S.C. §102 for anticipation, as all the claims under appeal have been disposed by the rejections under 35 U.S.C. §101 for lack of utility and 35 U.S.C. §112 for lack of enablement.

Claim Grouping

According to appellants, the claims stand or fall together. (Brief, page 5). Since the individual claims are not argued, we decide this appeal with respect to the utility rejection on the basis of claim 18. 37 CFR §1.192(c)(7) (1998).

DISCUSSION

35 U.S.C. § 101

Claims 18-19 and 33-34 stand rejected under 35 U.S.C. 101 for lack of utility. Claims 18-19 and 33-34 stand rejected under 35 U.S.C. 112, first paragraph for lack of enablement.

The examiner argues that (Answer, page 4):

> [t]he claims are directed to a polypeptide comprising SEQ ID NO:1 and its variants in claim 18 where the polypeptide is a receptor for which the function is not known. Although the closest prior art (Falkenstein et al.) teach that the protein binds progesterone, the protein is not the traditional progesterone steroid receptor which translocates to the nucleus which is well known. Rather the protein is only identified by its binding characteristic which does not reveal its function. The specification as filed does not disclose or provide evidence that points to a property of the claimed receptor such that another non-asserted utility would be well established. Since the function of the protein is not known, the protein lacks well established utility... there is no nexus between the unknown properties and the treatment of the disease. Thus, the treatment of the disease lacks substantial utility because further research to identify or reasonably confirm a "real world" context of use is required.

Appellants' Argument

Appellants respond, arguing that "the rejections are based solely upon the unfounded assertion that the claimed polypeptide (CYSTAR) has no known function." Brief, page 6. Appellants argue that the claimed polypeptide "shares 79% amino acid identity with rat 25-Dx protein which is known to be responsive to dioxin. ... The rat 25-Dx protein was suggested to be a member of the cytokine/growth factor/prolactin receptor superfamily (see the specification, page 2, lines 4-22)." Id. Appellants argue that CYSTAR and rat 25-Dx protein have a similar hydrophobicity plot. CYSTAR also has 93% identity with porcine steroid membrane binding protein, which binds progesterone. Id. Based on this evidence, appellants argue that one of skill in the art would reasonably believe that CYSTAR is a cytokine/steroid receptor protein; in particular, that it is the human membrane bound progesterone receptor. Id.

In addition appellants argue that, "[a]t the time of filing, it was well known in the art that certain steroid effects occurred too rapidly to be caused by nuclear translocation and transcriptional modulation. These rapid, non-genomic steroid effects were understood to be due to a distinct class of membrane bound steroid receptors, since 'specific binding sites have been described in membranes for various steroids exposing pharmacological properties distinct from those of the intracellular receptors' (Falkenstein et al., page 86). See also the specification, page 3, and the reference of

record (M. Wehling, (1977) 'Specific Nongenomic Actions of Steroid Hormones' Ann. Rev. Physiol., 59:365-393)." Brief, page 7.

Appellants conclude that "the examiner has not met the burden to demonstrate that a person of ordinary skill in the art would reasonably doubt the asserted utility of the claimed invention." Brief, page 9.

The examiner responds, arguing that Wehling, to the contrary, states that "progesterone was known to cause non-genomic actions including effects on oocyte maturation and the spermatozoan acrosome reaction" and that "the rapid non-genomic effect of progesterone on the spermatozoan acrosome reaction has been questioned recently and future research must delineate the conditions under which progesterone activates the acrosome reaction, if at all." Answer, page 8. According to the examiner, Wehling "indicates that there is doubt as to the progesterone effect and need for further experimentation which lacks substantial utility." Id., at 8-9.

The examiner further notes that "the percent identity of amino acid sequence between CYSTAR and rat 25-Dx is much lower than the CYSTAR percent identity of amino acid sequence comparison with progesterone binding protein." The examiner finds that "underlying the difference in structure is the different functions of progesterone binding protein and 25-Dx, since the progesterone binding protein

appears to bind progesterone while 25-Dx appears to be induced by dioxin, TCDD, but whose physiological function is not known. Thus, there is no nexus between the CYSTAR protein and rat 25-Dx protein in function since the rat 25Dx is an orphan protein. No evidence has been provided that CYSTAR is responsive to dioxin or TCDD. Appellants further link homology to IL-6 receptor due to homology in the transmembrane receptor. However, there is no evidence that the claimed CYSTAR protein is related to interleukin-6 receptors in function." Answer, pages 9-10.

Finally, the examiner states that U.S. Patent No. 5,976,837 to Jacobs argued by appellants (and cited by the examiner as prior art) has not been considered because appellants did not establish under 37 CFR 1.195 good and sufficient reasons why the reference was not earlier presented in support of enablement. Answer, page 9.

Appellants do not reply to the argument and issues raised by the examiner.

Analysis

We find that the asserted utility of the claimed invention does not satisfy the utility requirement of § 101. We agree with the examiner that appellants have failed to show a sufficient nexus or relationship between the 25-Dx protein and the progesterone binding protein functions to support a utility for the claimed CYSTAR polypeptide.

Nor do we find Wehling to be evidence which tips the balance in favor of a finding of utility in the present case. Wehling leaves open many questions as to whether there is a nongenomic effect of progesterone on the spermatozoan acrosome reaction and suggests that future research is required to verify such a conclusion. Wehling, pages 365 and 386.

In addition, the specification itself recognized that "it is still highly speculative whether these [TCDD-responsive genes][1] are actively involved in carcinogenesis." Specification, page 1. Thus, we do not find any described correlation in the specification between rat 25Dx, a TCDD responsive protein, and CYSTAR which provides support for the diagnosis or treatment of "cancers of [the] glands, tissues, and organs involved in secretion or absorption such as prostate, lung, bladder, adrenal gland, liver, uterus, kidney; and cancers of tissues of the immune and hematopoietic systems." Specification, pages 25-26.

Nor do we find the specification, through any described relationship between the claimed CYSTAR polypeptide to rat 25Dx or the porcine progesterone binding protein, provides support for the treatment or diagnosis of inflammatory disorders with the claimed CYSTAR polypeptide.

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[1] TCDD is an abbreviation for tetra-chlorodibenzo-p-dioxin. Appellants argue 25Dx is a TCDD responsive gene.

Finally, the fact that TCDD responsive genes in general, and CYSTAR in particular, are members of the P450 superfamily does not reasonably convey or correlate any specific function to the CYSTAR polypeptide. The specification, page 1, states that the P450 superfamily includes proteins with many distinct and varying functions. For example, the P450 superfamily includes "metabolic pathway enzymes, growth factor receptors, including epidermal growth factor receptor, and several proteins associated with proinflammatory states such as interleukin 1B and plasminogen activator inhibitor 2..." Thus, since no function has been conclusively attributed to the CYSTAR polypeptide it could have any of the above functions, or no function in common with the superfamily members. Furthermore, the fact that molecules that interact with CYSTAR can be determined using CYSTAR specific antibodies is of no further consequence, when no function or use can be attributed to the CYSTAR polypeptide.

Nor do we find use of the polypeptide in expression profiling, drug or toxicology testing or microarrays provides a specific benefit in currently available form, as no particular use or function can be attributed to the polypeptide, once identified in a microarray. We cannot agree with Appellants' argument set forth in the Brief, page 11.

First, the specification's disclosure regarding expression profiling and drug or toxicology testing is found on pages 38-40. That disclosure states only that CYSTAR, its catalytic or immunogenic fragments... "can be used for screening libraries of compounds in any of a variety of drug screening techniques." Specification, page 40.

Appellants also argue that an additional use for CYSTAR is in gene and protein expression profiling. Brief, page 10. See also, specification page 38.

According to Appellants, "the amino acid sequences of expressed polypeptides are tools essential to any technology that uses proteome expression profiling." Brief, page 10. We cannot agree with Appellants' position. The specification contains no specific disclosure regarding the use of CYSTAR in "expression profiling," or "proteome expression profiling". The closest the specification comes to disclosing the use of CYSTAR in "toxicology testing" or "drug discovery" is the disclosure that CYSTAR can be used in "drug screening" to identify compounds that bind to, or are bound by, CYSTAR. See specification, page 40.

This disclosure is inadequate to show utility for the claimed CYSTAR polypeptides, because the record provides no basis on which to use "drugs" that bind to CYSTAR in any kind of therapy. While the specification contains an extensive list of cancers and inflammation-associated diseases, it provides no evidence that CYSTAR is associated with any specific disorder, causatively or otherwise. Thus, the specification's suggestion that CYSTAR could be used to identify compounds that bind to CYSTAR does not suffice to show utility of the claimed polypeptides.

Appellants argue that the use of polynucleotides and polypeptides in expression profiling is "well-established" and therefore need not be expressly disclosed in the specification. See the Appeal Brief, page 10. Appellants provide no timely filed evidence to support this position.

Assuming arguendo that the use of polypeptides to monitor gene expression in research related to toxicology testing, drug development, and disease diagnosis was well-established as the application's filing date, we do not find Appellants' argument persuasive. We find that merely using the claimed polypeptides to monitor changes in gene expression would not satisfy § 101's utility requirement, as it has been interpreted by the courts.

The seminal decision interpreting the utility requirement of § 101 is Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966). At issue in Brenner was a claim to "a chemical process which yields an already known product whose utility—other than as a possible object of scientific inquiry—ha[d] not yet been evidenced." Id. at 529, 148 USPQ at 693. The Patent Office had rejected the claimed process for lack of utility, on the basis that the product produced by the claimed process had not been shown to be useful. See id. at 521-22, 148 USPQ at 690. On appeal, the Court of Customs and Patent Appeals reversed, on the basis that "where a claimed process produces a known product it is not necessary to show utility for the product." Id. at 522, 148 USPQ at 691.

The Brenner Court noted that although § 101 requires that an invention be "useful," that "simple, everyday word can be pregnant with ambiguity when applied to the facts of life." Id. at 529, 148 USPQ at 693. Thus,

> [i]t is not remarkable that differences arise as to how the test of usefulness is to be applied to chemical processes. Even if we knew precisely what Congress meant in 1790 when it devised the "new and useful" phraseology and in subsequent re-enactments of the test, we

> should have difficulty in applying it in the context of contemporary chemistry, where research is as comprehensive as man's grasp and where little or nothing is wholly beyond the pale of "utility"—if that word is given its broadest reach.

Id. at 530, 148 USPQ at 694.[2]

The Court, finding "no specific assistance in the legislative materials underlying § 101," based its analysis on "the general intent of Congress, the purposes of the patent system, and the implications of a decision one way or the other." Id. at 532, 148 USPQ at 695. The Court concluded that "[t]he basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." Id. at 534-35, 148 USPQ at 695.

The Court considered and rejected the applicant's argument that attenuating the requirement of utility "would encourage inventors of new processes to publicize the event for the benefit of the entire scientific community, thus widening the search for uses and increasing the fund of scientific knowledge." The Court noted that, while there

[2] The invention at issue in Brenner was a process, but the Court expressly noted that its holding "would apply equally to the patenting of the product produced by the process." Id. at 535, 148 USPQ at 695-96.

is value to encouraging disclosure, "a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if

clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development." Id. at 534, 148 USPQ at 695.

The Court took pains to note that it did not "mean to disparage the importance of contributions to the fund of scientific information short of the invention of something 'useful,'" and that it was not "blind to the prospect that what now seems without 'use' may tomorrow command the grateful attention of the public." Id. at 535-36, 148 USPQ at 696. Those considerations did not sway the Court, however, because "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." Id.

Subsequent decisions of the CCPA and the Court of Appeals for the Federal Circuit have added further layers of judicial gloss to the meaning of § 101's utility requirement. The first opinion of the CCPA applying Brenner was In re Kirk, 376 F.2d 936, 153 USPQ 48 (CCPA 1967). The invention claimed in Kirk was a set of steroid derivatives said to have valuable biological properties and to be of value "in the

furtherance of steroidal research and in the application of steroidal materials to veterinary or medical practice." Id. at 938, 153 USPQ at 50. The claims had been rejected for lack of utility. In response, the applicants submitted an affidavit which purportedly "show[ed] that one skilled in the art would be able to determine the biological uses of the claimed compounds by routine tests." Id. at 939, 153 USPQ at 51.

The court held that "nebulous expressions [like] 'biological activity' or 'biological properties'" did not adequately convey how to use the claimed compounds. Id. at 941, 153 USPQ at 52. Nor did the applicants' affidavit help their case: "the sum and substance of the affidavit appear[ed] to be that one of ordinary skill in the art would know 'how to use' the compounds to find out in the first instance whether the compounds are—or are not—in fact useful or possess useful properties, and to ascertain what those properties are." Id. at 942, 153 USPQ at 53.

The Kirk court held that an earlier CCPA decision, holding that a chemical compound meets the requirements of § 101 if it is useful to chemists doing research on steroids, had effectively been overruled by Brenner. "There can be no doubt that the insubstantial, superficial nature of vague, general disclosures or arguments of 'useful in research' or 'useful as building blocks of value to the researcher' was recognized, and clearly rejected, by the Supreme Court" in Brenner. See Kirk, 376 F.2d at 945, 153 USPQ at 55.

More recently, in In re Ziegler, 992 F.2d 1197, 26 USPQ2d 1600 (Fed. Cir. 1993), the Federal Circuit considered the degree of specificity required to show utility for a claim to polypropylene. The U.S. application on appeal in Ziegler claimed priority to a German application filed in 1954. "In the German application, Ziegler disclosed only that solid granules of polypropylene could be pressed into a flexible film with a characteristic infrared spectrum and that the polypropylene was 'plastic-like.'" Id. at 1203, 26 USPQ2d at 1605. "Ziegler did not assert any practical use for the polypropylene or its film, and Ziegler did not disclose any characteristics of the polypropylene or its film that demonstrated its utility." Id. The court held that the German application did not satisfy the requirements of § 101 and therefore could not be relied on to overcome a rejection based on an intervening reference. See id., 26 USPQ2d at 1606. "[At] best, Ziegler was on the way to discovering a practical utility for polypropylene at the time of the filing of the German application; but in that application Ziegler had not yet gotten there." Id., 26 USPQ2d at 1605.

On the other hand, the CCPA reversed a rejection for lack of utility in In re Jolles, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980). The applicant in Jolles claimed pharmaceutical compositions that were disclosed to be useful in treating acute myeloblastic leukemia. See id. at 1323, 206 USPQ at 886. The active ingredients in the compositions were closely related to daunorubicin and doxorubicin, both of which were "well recognized in the art as valuable for use in cancer chemotherapy." Id., 206 USPQ at 887. The applicant also submitted declaratory evidence showing that eight of

the claimed compositions were effective in treating tumors in a mouse model, and one was effective in treating humans. See id. at 1323-24, 206 USPQ at 887-88. The court noted that the data derived from the mouse model were "relevant to the treatment of humans and [were] not to be disregarded," id. at 1327, 206 USPQ at 890, and held that the evidence was sufficient to support the asserted therapeutic utility. See id. at 1327-28, 206 USPQ at 891.

The Federal Circuit held in Cross v. Iizuka, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985), that in vivo testing (as in Jolles) was not necessarily required to show utility in the pharmaceutical context. The Cross court stated that "[it] is axiomatic that an invention cannot be considered 'useful,' in the sense that a patent can be granted on it, unless substantial or practical utility for the invention has been discovered and disclosed where such utility would not be obvious." Id. at 1044, 224 USPQ at 742 (citing Brenner v. Manson). The court "perceive[d] no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, in vitro testing, may establish a practical utility for the compound in question." Id. at 1051, 224 USPQ at 748. Successful in vitro testing could provide an immediate benefit to the public, by "marshal[ling] resources and direct[ing] the expenditure of effort to further in vivo testing of the most potent compounds . . ., analogous to the benefit provided by the showing of an in vivo utility." Id. On the facts of that case – successful in vitro testing supplemented by similar in vitro and in vivo activities of structurally similar compounds – the court held that in vitro activity was sufficient to meet the requirements of § 101. See

id.

The Federal Circuit confirmed in In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995), that human testing is not necessary to establish utility for a method of treatment. The invention claimed in Brana was a group of compounds disclosed to have antitumor activity. See id. at 1562, 34 USPQ2d at 1437-38. The specification disclosed that the claimed compounds had higher antitumor activity than related compounds known to have antitumor activity, and the applicants provided declaratory evidence of in vivo activity against tumors in a mouse model. See id., 34 USPQ2d at 1438. The court held that these data were sufficient to satisfy § 101; usefulness in patent law does not require that the invention be ready to be administered to humans. See id. at 1567, 34 USPQ2d at 1442.

Several lessons can be drawn from Brenner and its progeny. First, § 101's requirement that an invention be "useful" is not to be given its broadest reach, such that little or nothing of a chemical nature would be found to lack utility. See Brenner, 383 U.S. at 530, 148 USPQ at 694. Thus, not every "use" that can be asserted will be sufficient to satisfy § 101. For example, the steroid compound at issue in Brenner was useful as a possible object of scientific inquiry, and the polypropylene claimed in Ziegler was useful for pressing into a flexible film, yet both lacked sufficient utility to satisfy § 101. See Brenner, 383 U.S. at 529, 148 USPQ at 696; Ziegler, 992 F.2d at 1203, 26 USPQ2d at 1605.

Rather than setting a de minimis standard, § 101 requires a utility that is "substantial", i.e., one that provides a specific benefit in currently available form. Brenner, 383 U.S. at 534-35, 148 USPQ at 695. This standard has been found to be met by pharmaceutical compositions shown to be useful in mouse models and in humans for treating acute myeloblastic leukemia (Jolles, 628 F.2d at 1327-28, 206 USPQ at 891); by evidence showing successful in vitro testing supplemented by similar in vitro and in vivo activities of structurally similar compounds (Cross, 753 F.2d at 1051, 224 USPQ at 748); and by evidence showing in vivo antitumor activity in mice, combined with a disclosure that the claimed compounds had higher antitumor activity than a related compound known to have antitumor activity (Brana, 51 F.3d at 1567, 34 USPQ2d at 1442).

By contrast, Brenner's standard has been interpreted to mean that "vague, general disclosures or arguments of 'useful in research' or 'useful as building blocks of value to the researcher'" would not satisfy § 101. See Kirk, 376 F.2d at 945, 153 USPQ at 55 (interpreting Brenner). Likewise, a disclosure of a "plastic-like" polypropylene capable of being pressed into a flexible film was held to show that the applicant was "at best . . . on the way to discovering a practical utility for polypropylene at the time of the filing," but not yet there. Ziegler, 992 F.2d at 1203, 26 USPQ2d at 1605.

We find that the asserted utility of the claimed polypeptides—as one component of an assay for monitoring gene expression—does not satisfy the utility requirement of § 101. Such a use does not provide a specific benefit in currently available form.

We accept, for argument's sake, that a person skilled in the art could use the claimed CYSTAR polypeptide, in combination with other polypeptides, to monitor changes in expression of the gene that encodes CYSTAR. However, the specification provides no guidance to allow a skilled artisan to use data relating to CYSTAR expression in any practical way. The specification simply provides no guidance regarding what the CYSTAR-specific information derived from a gene expression experiment would mean.

Suppose, for example, that a researcher found that CYSTAR expression was increased when a cell was treated with a particular agent. The specification provides no basis on which a skilled worker would be able to determine whether that result is meaningful. Maybe the meaning in a change in CYSTAR expression would depend on other factors, but again the specification provides no hint what other factors might be important. Would it depend on what agent is used, what cell type is used, the behavior of other genes (if so, which genes and what behavior is significant), the degree of increase? The specification simply provides no guidance as to how to interpret the results that might be seen using CYSTAR in a gene expression assay.

In effect, Appellants' position is that the claimed polypeptides are useful because those of skill in the art could experiment with them and figure out for themselves what any observed experimental results might mean. We do not agree that such a disclosure provides a "specific benefit in currently available form." Rather, the instant case seems analogous to Brenner. In Brenner, the applicant claimed a method of

making a compound but disclosed no utility for the compound. 383 U.S. at 529, 148 USPQ at 693. The Court held that a process lacks utility if it produces a product that lacks utility. Id. at 534, 148 USPQ at 695. Here, the applicants claim a product asserted to be useful in a method of generating gene-expression data, but the specification does not disclose how to interpret those data. Just as the process claimed in Brenner lacked utility because the specification did not disclose how to use the end-product, the products claimed here lack utility, based on their use in gene expression assays, because the specification does not disclose how to use CYSTAR-specific gene expression data.

Here, Appellants assert that CYSTAR, along with every other expressed human gene or protein, can be used to monitor changes in gene expression. However, any observed results of changed expression of the CYSTAR-encoding gene would have no meaning without additional knowledge of what a change in expression of CYSTAR means. The specification in effect discloses that the claimed polypeptides can be used to monitor gene expression, and those of skill in the art will figure out what to do with the gene expression data. This utility is not substantial; it does not provide a specific benefit in currently available form.

Appellants' position may be that gene expression data have utility, and such data can be derived from thousands of polypeptides; therefore, since the polypeptides collectively provide the data, each one of the polypeptides has utility. We decline to attenuate the utility requirement to this degree.

Assuming arguendo that a generic gene expression assay—one based on monitoring expression of thousands of uncharacterized or semi-characterized polypeptides—would provide a useful tool for, e.g., drug discovery, it does not follow that each one of the polypeptides represented in the assay individually has patentable utility. Although each polypeptide in the assay contributes to the data generated by the assay overall, the contribution of a single polypeptide—its data point—is only a tiny contribution to the overall picture.

The Brenner Court held that § 101 sets more than a de minimis standard for utility. Therefore, the patentable utility of a gene expression assay, for example, does not necessarily mean that each tiny component of the assay also has patentable utility. A patentable utility divided by a thousand does not necessarily equal a thousand patentable utilities. Each claimed invention must be shown to meet § 101's utility requirement in order to be patentable; it must provide a specific benefit in currently available form. Providing a single data point among thousands or millions, even if the thousands or millions of data points collectively are useful, does not meet this standard.

The Supreme Court noted that the patent system contemplates a basic quid pro quo: in exchange for the legal right to exclude others from his invention for a period of time, an inventor discloses his invention to the public. See Brenner, 383 U.S. at 534, 148 USPQ at 695. The Brenner Court held that the grant of patent rights to an applicant is justified only by disclosure of an invention with substantial utility – a specific benefit in currently available form. Until the invention has been refined and developed to this point, the Court held, the applicant has not met his side of the bargain, and has not provided a disclosure sufficient to justify a grant of the right to exclude others. See id.

In this case, Appellants seek the right to exclude others from using the claimed invention, which includes

- the amino acid sequence of SEQ ID NO:1;
- a naturally-occurring amino acid sequence having at least 95% sequence identity to the sequence of SEQ ID NO:1, wherein said amino acid sequence encodes a polypeptide whose expression is upregulated by 2,3,7,8,-Tetrachlorodibenzo-p-dioxin,
- a biologically-active fragment of the amino acid sequence of SEQ ID NO:1, wherein said fragment encodes a polypeptide whose expression is upregulated by 2,3,7,8,-Tetrachlorodibenzo-p-dioxin, and
- an immunologically active fragment of the amino acid sequence of SEQ ID NO:1 wherein said fragment generates an antibody that specifically binds to the polypeptide encoded by SEQ ID NO:1.

In return for the right to exclude others from using all of these products, Appellants contend that it is enough for them to simply disclose the structure of the claimed polypeptides. See the Appeal Brief, pages 6-9. We do not agree that such a disclosure satisfies § 101. The basic quid pro quo of the patent system, as interpreted

by the Brenner Court, is the grant of a valuable legal right in exchange for a meaningful disclosure of the claimed invention. Appellants' bare-bones disclosure in this case does not entitle them to the legal right they claim.

The polypeptides of the instant claims may indeed prove to be very useful (and valuable), after the in vivo role of the encoded protein is discovered. The work required to confer value on CYSTAR, however, remains to be done. The instant specification's CYSTAR-specific disclosure does not justify a grant of patent rights. See Brenner, 383 U.S. at 534, 148 USPQ at 695: "[A] process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development." We consider the Brenner Court's concern about the "power to block off whole areas of scientific development" equally applicable here.

According to Appellants, the microarray technique is applicable to proteins. This reasoning—that fragments of proteins can be fixed to a surface and used to screen compounds for binding to other compounds—cannot logically be confined to the proteins themselves. By extension, the compounds of interest could also be affixed to a surface (i.e., a microarray) and exposed to cellular proteins, in order to assay for

binding in the same manner. It would seem, therefore, that Appellants' argument would require a finding of utility for any compound which might bind or be bound by any other compound of physiological significance.

It is apparent, therefore, that Appellants' proposed rule would vitiate the statutory utility requirement for most chemical compounds. If Appellants' reasoning were adopted, it would result in a per se rule that all chemical compounds have utility because each one can be used to do research on others.

Appellants' reasoning would also vitiate the enablement requirement, since "[t]he enablement requirement is met if the description enables any mode of making and using the invention." Johns Hopkins Univ. v. CellPro Inc., 152 F.3d 1342, 1361, 47 USPQ2d 1705, 1714 (Fed. Cir. 1998) (quoting Engel Indus., Inc. v. Lockformer Co., 946 F.2d 1528, 1533, 20 USPQ2d 1300, 1304 (Fed. Cir. 1991)). If we were to agree with Appellants that any expressed gene, any six base pair-long fragment thereof, and any expressed protein is useful in a microarray, then we would also have to hold that the specification has taught those skilled in the art one mode of using the invention. Thus, Appellants' rule of per se utility would also require a corresponding rule of per se enablement.

What limit then would remain on patenting of genes and proteins (and potentially any other bioactive compound)? It would seem that under Appellants' rule, a compound would be patentable if it was adequately described in the specification and was not disclosed or suggested in the prior art. This standard, however, is not the one

set by Congress, which requires that a patentable invention also be useful and fully enabled, nor is it the standard that has been consistently applied by the courts.

As another matter, we note we have not considered U.S. Patent No. 5,976,837 to Jacobs proffered by appellants as the examiner has determined that appellants have not complied with 37 CFR 1.195 showing good and sufficient reasons why the reference was not earlier presented. We agree with the examiner that the specification as filed does not disclose or provide evidence of sufficient common structure with another polypeptide of known function in such a manner to establish a utility for the CYSTAR polypeptide. We do not find appellants have provided a specific benefit in currently available form for the claimed CYSTAR polypeptide.

The patent system is based on a balancing of interests. "Patents . . . are meant to encourage invention by rewarding the inventor with the right, limited to a term of years fixed by the patent, to exclude others from the use of his invention. . . . But in rewarding useful invention, the 'rights and welfare of the community must be fairly dealt with and effectually guarded.' Kendall v. Winsor, 21 How. 322, 329 (1859). To that end the prerequisites to obtaining a patent are strictly observed. . . . To begin with, a genuine 'invention' or 'discovery' must be demonstrated 'lest in the constant demand for new appliances the heavy hand of tribute be laid on each slight technological advance in an art.'" Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 230, 140 USPQ 524, 527 (1964).

The basic quid pro quo of the patent system requires disclosure of an invention having substantial utility. Appellants' disclosure in this case does not provide a specific benefit in currently available form, and therefore lacks the substantial utility required by 35 U.S.C. § 101. The rejection of the claims under 35 U.S.C. § 101 is affirmed. We also affirm the rejection of the claims for lack of enablement under 35 U.S.C. §112, first paragraph, for lack of enablement.[3]

Written Description

Claims 18 and 33 stand rejected under 35 U.S.C. 112, first paragraph for lack of written description in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. We find it unnecessary to reach the rejections for lack of written description and for anticipation on the merits as we find the affirmance of the rejections of the claims for lack of utility and enablement disposes of the appeal. 37 CFR 1.196(a).

[3] The cases of In re Fouche, 439 F.2d 1237, 1243, 169 USPQ 429, 434 (CCPA 1971) and In re Brana, 51 F.3d 1560, 1563, 34 USPQ2d 1436, 1439 (Fed. Cir. 1995), recognize that 35 U.S.C. §101 rejections for utility present similar issues as 35 U.S.C. §112 rejections for nonenablement. According to Fouche if "compositions are in fact useless, appellant's specification cannot have taught how to use them." 439 F.2d at 1243, 169 USPQ at 434.

Prior Art

We find it unnecessary to reach the rejections based on prior art. The affirmance of the rejections of the claims for lack of utility and enablement disposes of the appeal.

CONCLUSION

We affirm the rejections of claims 18-19 and 33-34 under 35 U.S.C. §101 for lack of utility and 35 U.S.C. §112 for lack of enablement. We do not reach the rejections under 35 U.S.C. §112 for lack of written description and 35 U.S.C. §102 for anticipation, as all the claims have been disposed of in the appeal by the rejections under 35 U.S.C. §101 for lack of utility and 35 U.S.C. §112 for lack of enablement.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

WILLIAM F. SMITH
Administrative Patent Judge

DEMETRA J. MILLS
Administrative Patent Judge

ERIC GRIMES
Administrative Patent Judge

) BOARD OF PATENT
) APPEALS AND
) INTERFERENCES

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